

DAVID H. BERNSTEIN (NY Bar No. 2341071) (appearance *pro hac vice*)  
 JEREMY FEIGELSON (NY Bar No. 2518421) (appearance *pro hac vice*)  
 RUSHMI BHASKARAN (NY Bar No. 4794111) (admitted *pro hac vice*)  
 AMANDA BARTLETT (NY Bar No. 4793402) (admitted *pro hac vice*)

**DEBEVOISE & PLIMPTON LLP**

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 Email: wmetlitzky@conradmetlitzky.com

Attorneys for Defendant/Counterclaimant  
 FOUNDATION MEDICINE, INC.

UNITED STATES DISTRICT COURT  
 NORTHERN DISTRICT OF CALIFORNIA  
 SAN FRANCISCO DIVISION

GUARDANT HEALTH, INC.,

Plaintiff/Counterdefendant,

v.

FOUNDATION MEDICINE, INC.,

Defendant/Counterclaimant.

CASE NO. C 17-03590-JSC

**SURREPLY DECLARATION OF  
 AMANDA M. BARTLETT IN SUPPORT  
 OF FOUNDATION MEDICINE, INC.'S  
 SURREPLY MEMORANDUM**

Date: March 14, 2018  
 Time: 9:00 a.m.  
 Judge: Hon. Jacqueline Scott Corley  
 Courtroom: Courtroom F, 15th Floor

**[PUBLIC REDACTED VERSION]**

1 I, AMANDA M. BARTLETT, hereby declare as follows:

2 1. I have been admitted *pro hac vice* to appear before this Court. I am an associate at  
3 Debevoise & Plimpton LLP, counsel to the Defendant/Counterclaimant in this action. I submit this  
4 declaration in support of Defendant/Counterclaimant Foundation Medicine, Inc.'s Surreply  
5 Memorandum. The exhibit numbers in this Declaration continue from the point at which my earlier  
6 filed Declaration ended.

7 2. Attached hereto as **Exhibit 43** are additional true and correct excerpts from the transcript  
8 of the deposition of Dr. Helmy Eltoukhy in the above-captioned matter.

9 3. Attached hereto as **Exhibit 44** are additional true and correct excerpts from the transcript  
10 of the deposition of Mark Jacobstein in the above-captioned matter.

11 4. Attached hereto as **Exhibit 45** is a true and correct copy of a document produced by  
12 Foundation Medicine, Inc. in this matter bearing bates numbers FMI00001249-50.

13 5. Attached hereto as **Exhibit 46** are additional true and correct excerpts from the transcript  
14 of the deposition of Dr. Victoria Wang in the above-captioned matter.

15 6. Attached hereto as **Exhibit 47** is a true and correct excerpt of a spreadsheet produced by  
16 Guardant Health, Inc. in this matter bearing bates number GHI00001139, accompanied by a chart  
17 prepared by FMI's counsel based on the contents of that excerpt.

18 7. Attached hereto as **Exhibit 48** are true and correct excerpts from the transcript of the  
19 deposition of Dr. Philip Stephens in the above-captioned matter.

20 8. Attached hereto as **Exhibit 49** are additional true and correct excerpts from the transcript  
21 of the deposition of Dr. Siraj Mahamed Ali in the above-captioned matter.

22 9. Attached hereto as **Exhibit 50** is a true and correct copy of a document produced by  
23 Guardant Health, Inc. in this matter bearing bates numbers GHI00037189-91.

24 10. Attached hereto as **Exhibit 51** is a true and correct copy the list of speakers who  
25 participated in the World CB&CDx 2017 Conference, retrieved from [http://world-](http://world-cdx.com/about/speakers/)  
26 [cdx.com/about/speakers/](http://world-cdx.com/about/speakers/) on February 27, 2018.

27 11. Attached hereto as **Exhibit 52** is a true and correct copy of a document produced by  
28 Guardant Health, Inc. in this matter bearing bates numbers GHI00074814-15.



1           12. Attached hereto as **Exhibit 53** is a true and correct copy of a document produced by  
2 Guardant Health, Inc. in this matter bearing bates numbers GHI00037501-02.

3           13. Attached hereto as **Exhibit 54** are additional true and correct excerpts from the transcript  
4 of the deposition of Dr. Garrett Frampton in the above-captioned matter.

5           14. Attached hereto as **Exhibit 55** is a true and correct copy of a document produced by  
6 Foundation Medicine, Inc. in this matter bearing bates numbers FMI00087352-53.

7           15. Attached hereto as **Exhibit 56** is a true and correct copy of Exhibit 7 to the Declaration of  
8 Dr. Garrett Frampton, dated December 22, 2017, submitted in support of Foundation Medicine Inc.'s  
9 Motion for Preliminary Injunction in the above-captioned matter. (ECF. No. 111-1).

10           16. Attached hereto as **Exhibit 57** is a true and correct copy of a document produced by  
11 Guardant Health, Inc. in this matter bearing bates number GHI00096199.

12           17. Attached hereto as **Exhibit 58** is a true and correct copy of a document produced by  
13 Guardant Health, Inc. in this matter bearing bates numbers GHI00096201-02.

14  
15 I declare under penalty of perjury that the foregoing is true and correct. Executed in New York, New  
16 York on this 28th day of February, 2018.

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AMANDA M. BARTLETT

# EXHIBIT 43

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN FRANCISCO DIVISION

---oOo---

GUARDANT HEALTH, a Delaware  
corporation,

Plaintiff,

vs.

No. 3:17-cv-3590

FOUNDATION MEDICINE, INC., a  
Delaware corporation,

Defendant.

\_\_\_\_\_/

HIGHLY CONFIDENTIAL - OUTSIDE ATTORNEYS' EYES ONLY

VIDEOTAPED DEPOSITION OF

HELMY ELTOUKHY, PH.D.

\_\_\_\_\_  
(30(B)(6) DESIGNEE, GUARDANT HEALTH, INC.)

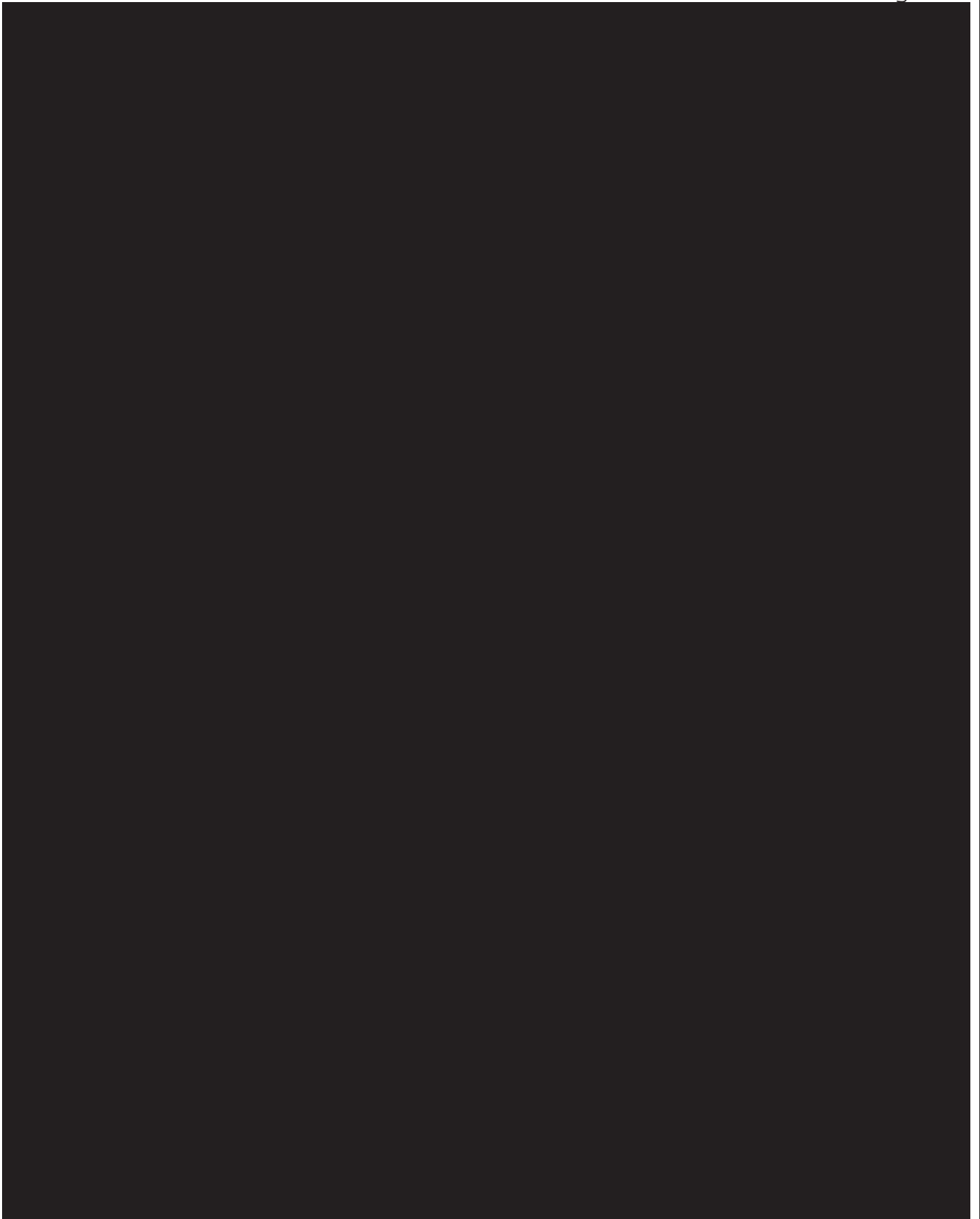
WEDNESDAY, FEBRUARY 7, 2018

REPORTED BY: HOLLY THUMAN, CSR No. 6834, RMR, CRR

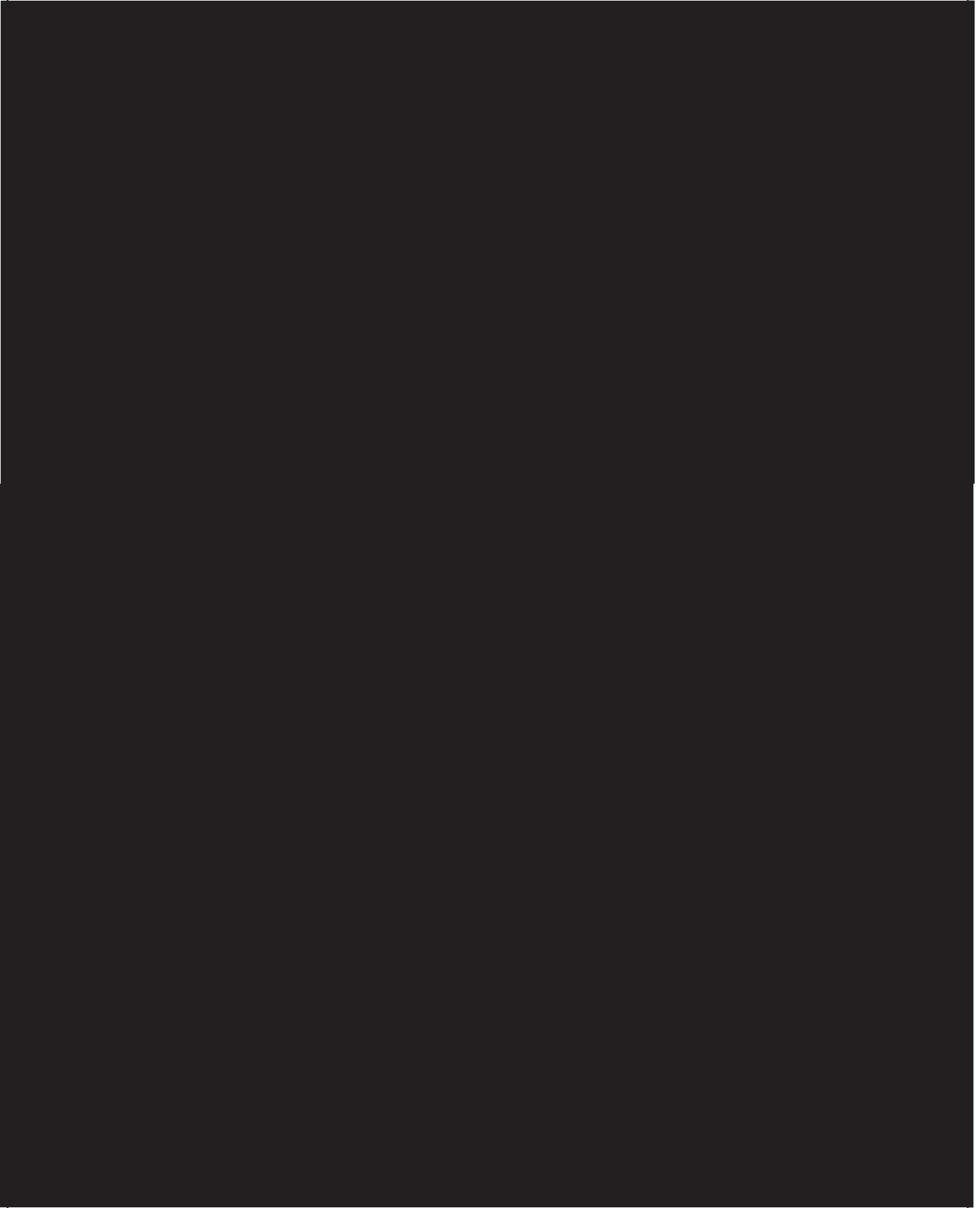
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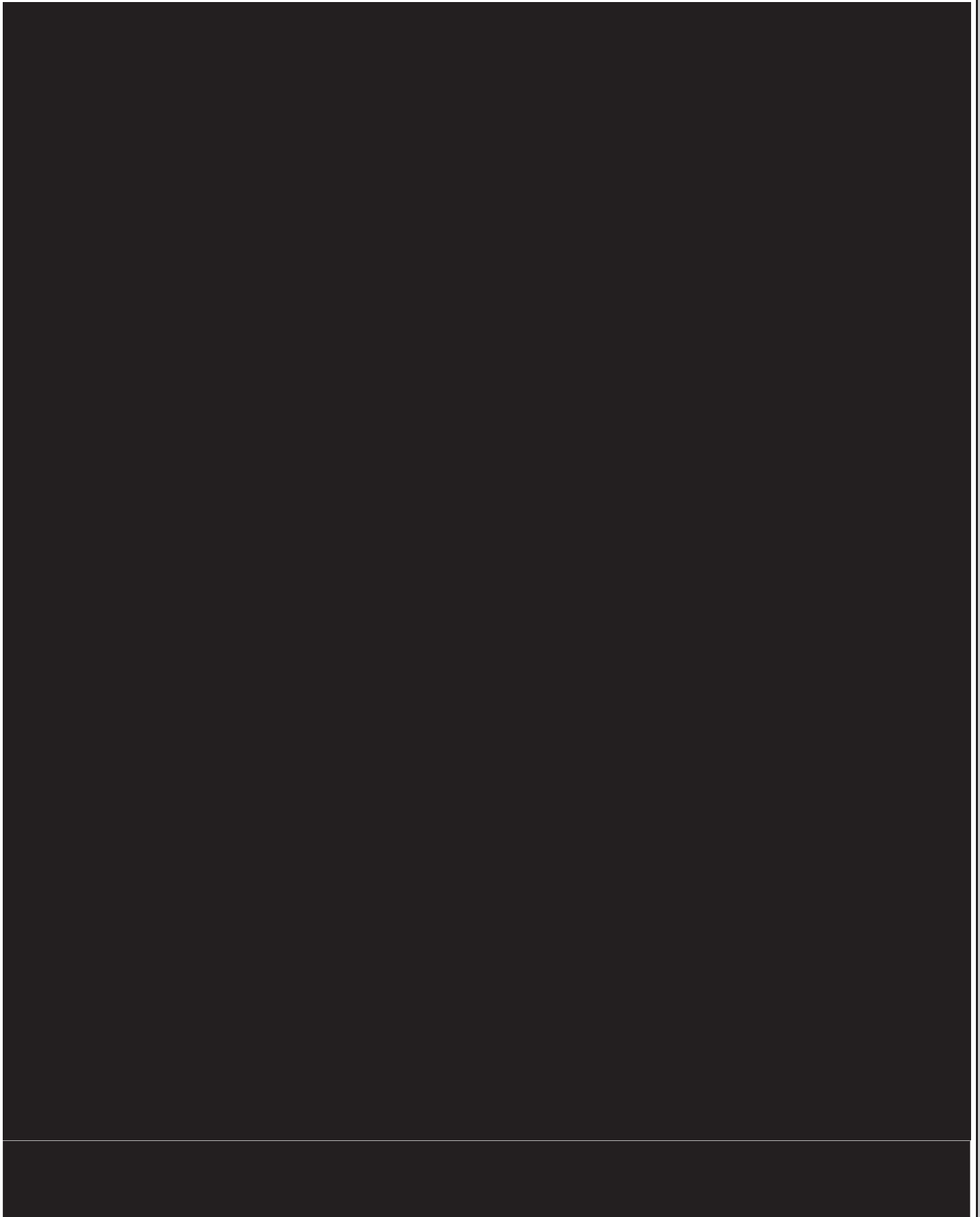


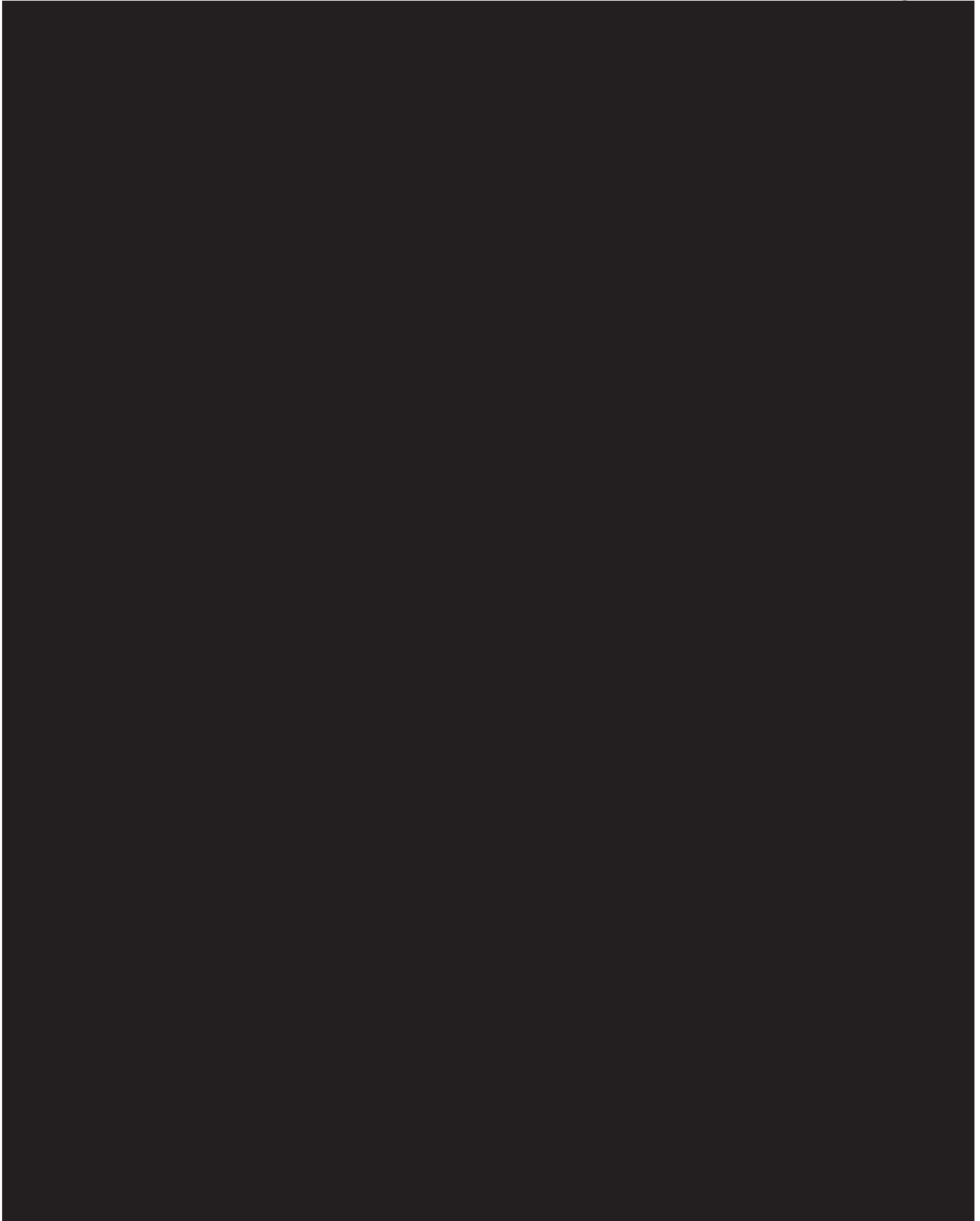




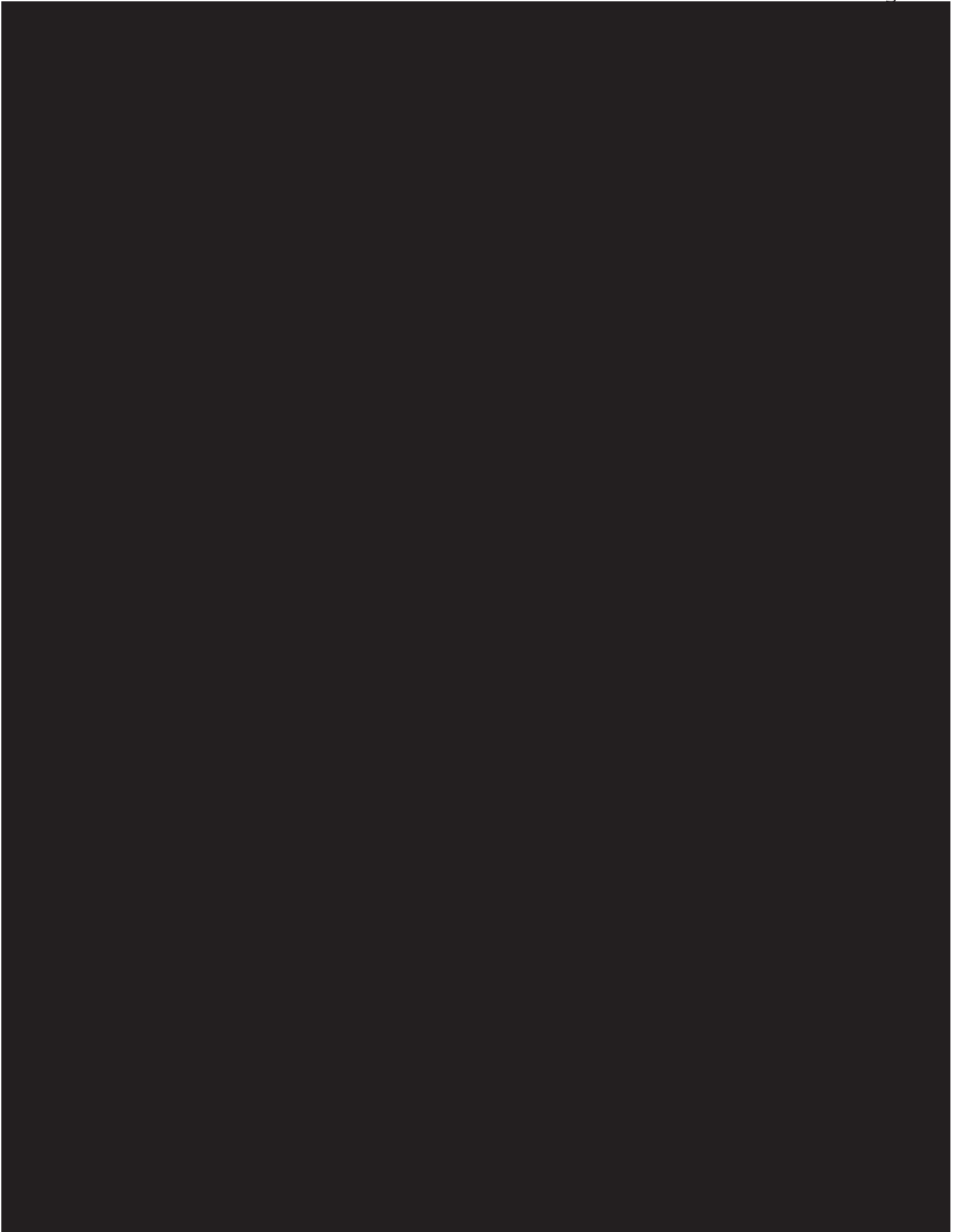












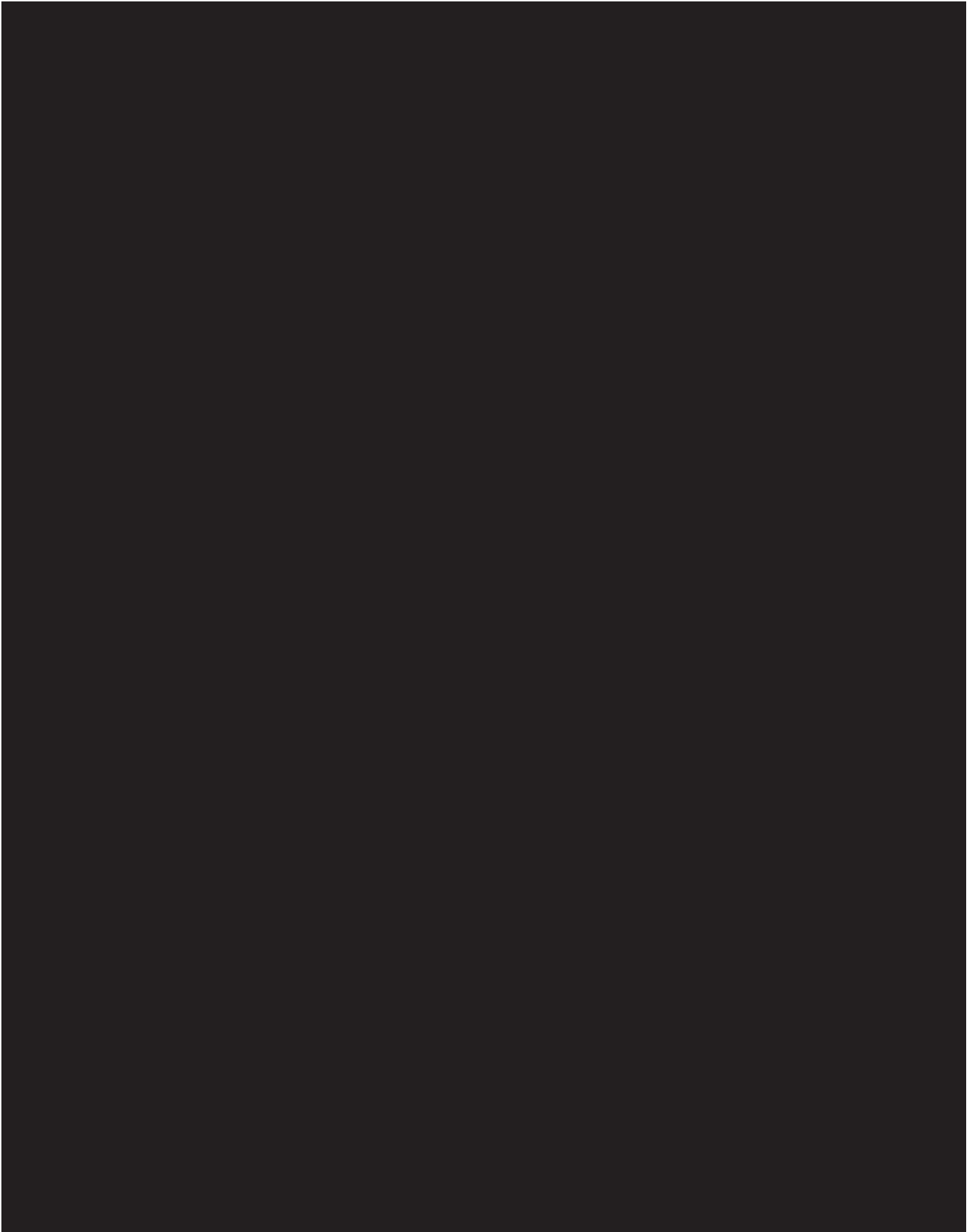


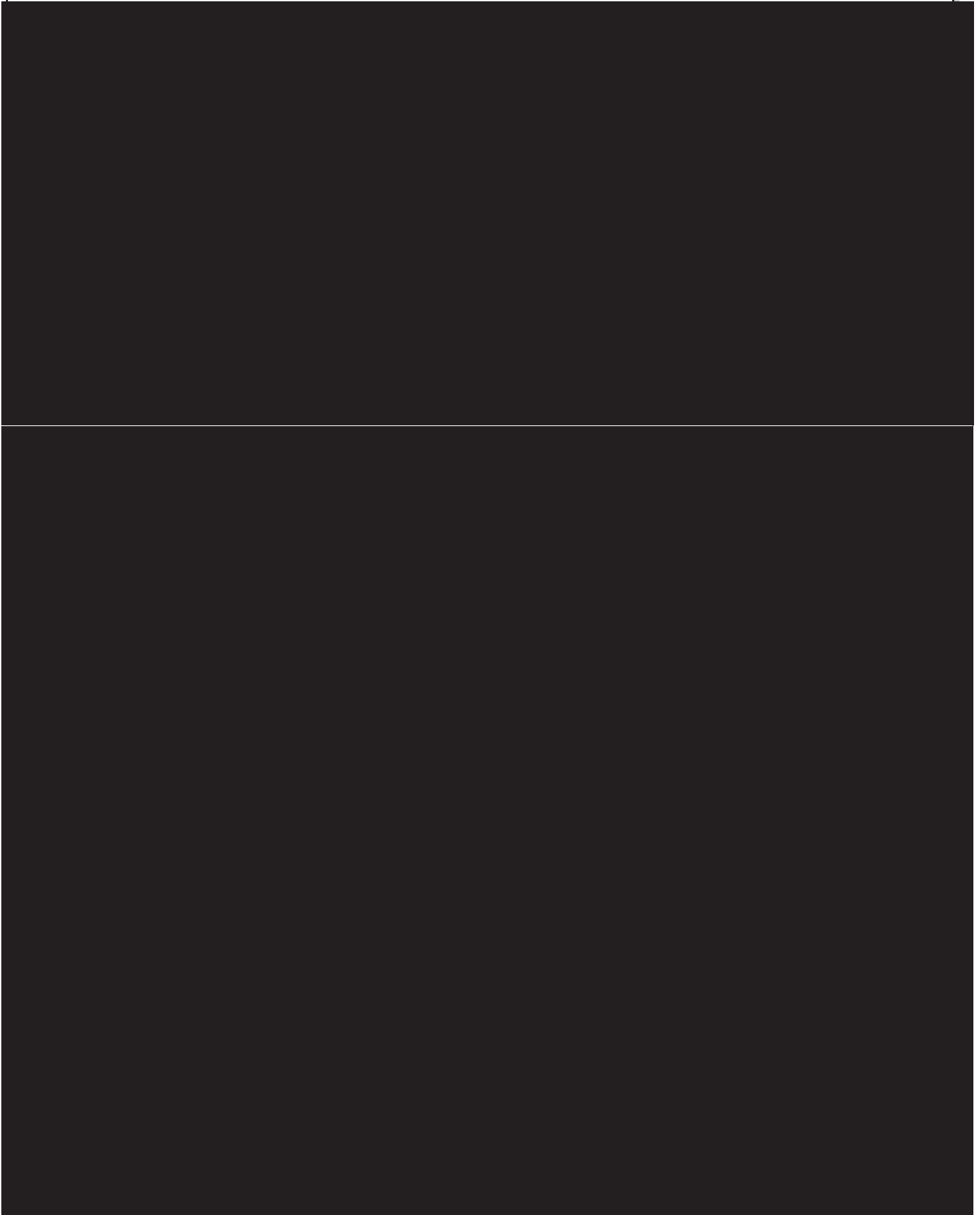












## 1 CERTIFICATE OF REPORTER

2 I, HOLLY THUMAN, a Certified Shorthand  
3 Reporter, hereby certify that the witness in the  
4 foregoing deposition was by me duly sworn to tell  
5 the truth, the whole truth, and nothing but the  
6 truth in the within-entitled cause; that said  
7 deposition was taken down in shorthand by me, a  
8 disinterested person, at the time and place therein  
9 stated; and that the testimony of said witness was  
10 thereafter reduced to typewriting, by computer,  
11 under my direction and supervision;

12 That before completion of the deposition  
13 review of the transcript [X] was [] was not  
14 requested/offered. If requested, any changes made  
15 by the deponent (and provided to the reporter)  
16 during the period allowed are appended hereto.

17 I further certify that I am not of counsel or  
18 attorney for either or any of the parties to the  
19 said deposition, nor in any way interested in the  
20 event of this cause, and that I am not related to  
21 any of the parties thereto.

22

23 DATED: February 8, 2018

24

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HOLLY THUMAN, CSR

25



# EXHIBIT 44

1 UNITED STATES DISTRICT COURT  
2 NORTHERN DISTRICT OF CALIFORNIA  
3 SAN FRANCISCO DIVISION  
4

5 GUARDANT HEALTH, INC., a  
6 Delaware corporation,

7 Plaintiff/Counterclaim Defendant,

8 vs.

No. 3:17-cv-3590

9 FOUNDATION MEDICINE, INC., a  
10 Delaware corporation,

11 Defendant/Counterclaimant.  
12 \_\_\_\_\_/

13 \*\*\* HIGHLY CONFIDENTIAL \*\*\*  
14

15 DEPOSITION OF MARK JACOBSTEIN  
16 (personally and as 30(b)(6) representative  
17 of Guardant Health, Inc.)  
18

19 January 29, 2018  
20  
21  
22

23 Reported by:  
24 Natalie Y. Botelho  
25 CSR No. 9897

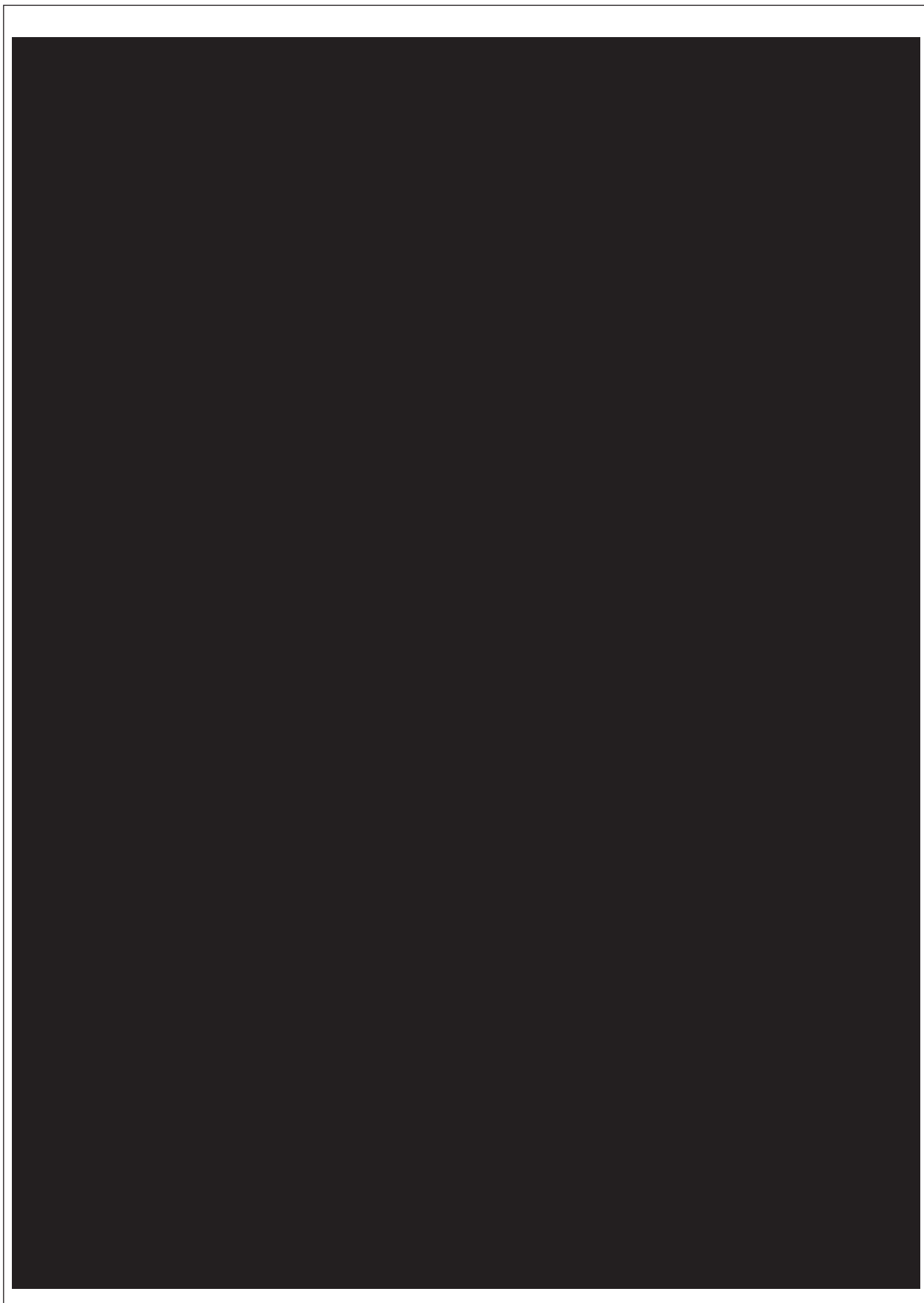














HIGHLY CONFIDENTIAL  
MARK JACOBSTEIN - 30(B)(6) - 01/29/2018

Page 281

## 1 CERTIFICATE OF REPORTER

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3 I, Natalie Y. Botelho, a Certified  
4 Shorthand Reporter, hereby certify that the witness  
5 in the foregoing deposition was by me duly sworn to  
6 tell the truth, the whole truth, and nothing but the  
7 truth in the within-entitled.

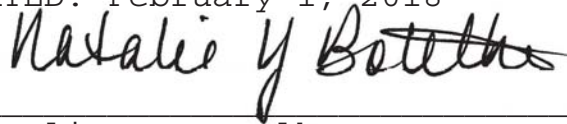
8 The said deposition was taken down in  
9 shorthand by me, a disinterested person, at the time  
10 and place therein stated, and that the testimony of  
11 said witness was thereafter reduced to typewriting,  
12 by computer, under my direction and supervision;

13 That before completion of the deposition,  
14 review of the transcript [ ] was [X] was not  
15 requested. If requested, any changes made by the  
16 deponent (and provided to the reporter) during the  
17 period allowed are appended hereto.

18 I further certify that I am not of counsel  
19 or attorney for either or any of the parties to the  
20 said deposition, nor in any way interested in the  
21 event of this cause, and that I am not related to  
22 any of the parties thereto.

23 DATED: February 1, 2018

24



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Natalie Y. Botelho, CSR No. 9897

# EXHIBIT 45



**Guardant360:**  
Extensively validated  
in the lab, by leading  
cancer centers, and by  
community oncologists

Guardant360® has been the most validated comprehensive liquid biopsy since its commercial introduction in 2014. Today, after **20,000** clinical samples, Guardant Health has contributed to **7** peer-reviewed publications and more than **60** abstracts and posters at scientific conferences such as ASCO, AACR, and SABCS. Guardant360 is used by the vast majority of leading cancer centers.

### Academia

Doctors at almost all NCI comprehensive cancer centers use Guardant360. Our collaborators have extensively validated Guardant360 through their research and clinical practice, and presented their findings at conferences such as ASCO and AACR.

For a partial list of Guardant360's scientific contributions, see the reverse side.

### Community

More than half our clinical sample volume comes from community oncologists. We serve medical oncologists in 46 out of 50 states.

Analytical, clinical validation  
through peer-reviewed publication

ANALYTIC SPECIFICITY **99.9999%**

SENSITIVE DETECTION **<0.1%**

COMMERCIAL INTRODUCTION **2014**



### Questions to ask about any liquid biopsy

How many doctors use this test?

- More than 2,500 oncologists order Guardant360

Where can I read your analytical and clinical validation study?

- Guardant Health published this study in *PLOS ONE* in 2015

Which biopharma companies use your test in their clinical trials?

- Guardant Health works with nearly two dozen drug companies to power their clinical trials



# Guardant360: Publications and Abstracts

Circulating cell-free DNA profiling of patients with advanced urothelial carcinoma of the bladder  
**ASCO 2016 Rebecca Nagy et al.**

Role of genomic instability in immunotherapy with checkpoint inhibitors  
**ASCO 2016 George Yaghoor et al.**

Prospective evaluation of circulating cell-free DNA sequencing in patients with metastatic renal cell carcinoma treated with pazopanib plus abiraterone  
**ASCO 2016 Jim Leng et al.**

Investigating the utility of comprehensive genomic profiling for patients with newly diagnosed breast cancer  
**ASCO 2016 Casey B. Williams et al.**

Profiling of circulating tumor (ct) DNA for potentially actionable targets in prostate cancer (PCa)  
**ASCO 2016 Guru Sonaev et al.**

Detection, frequency and actionability of recurrent copy number gains detected by non-invasive liquid biopsy of 3,942 lung and breast cancer samples  
**ASCO 2016 Diana Abdeeva et al.**

Early, molecular detection of cancer utilizing circulating cell-free DNA assay with ultra high accuracy and sensitivity  
**ASCO 2016 Stefanie Mortimer et al.**

Functional characterization of VUS mutations found in patients' cell-free circulating tumor DNA (ctDNA) using Precision Cancer Analysis System (PCAS)  
**ASCO 2016 Gabi Tarcic et al.**

Cell-free DNA sequencing-guided therapy in a prospective clinical trial: NEXT 2 trial - A feasibility analysis  
**ASCO 2016 Jeeyun Lee et al.**

Plasma T790M result alters treatment options in a previously T790 wild-type EGFR-mutant patient  
**Journal of Thoracic Oncology, 2016 Zofia Piotrowska, Benjamin Drapkin, Jeffrey A. Engelman, Rebecca J. Nagy, Richard B. Lanman, Lecia V. Sequist**

Comparison of over 10,000 clinical NGS circulating tumor DNA profiles to tissue-derived genomic compendia  
**AACR 2016 Abstract Oliver A. Zill, Kimberly C. Banks, Coyt Jackson, Stefanie Mortimer, Arthur Baca, Becky Nagy, Richard B. Lanman, Helmy Eltoukhy, AmirAli Talasz**

Salvage MET amplification detection and therapy through cell-free DNA NGS in a progressing lung cancer patient  
**AACR 2016 Abstract Nir Peled, Anna Bellowski, Lior Scoussan-Gutman, Richard B. Lanman, AmirAli Talasz**

Managing metastatic breast cancer via serial monitoring with circulating cell-free tumor DNA next generation sequencing testing  
**AACR 2016 Abstract Laura Austin, Rebecca Nagy, Oliver Zill, Richard B. Lanman, AmirAli Talasz, Massimo Cristofanilli**

Post-surgical resection monitoring in early stage colorectal carcinoma patients using a circulating cell-free DNA assay with ultra-high accuracy and specificity  
**AACR 2016 Abstract Stefanie A. Mortimer, Katharine Dilger, Stephen Fairclough, Diana Abdeeva, Darya Chudova, Ankit Sarin, Jim Leng, Jeeyun Lee, Helmy Eltoukhy, AmirAli Talasz**

A case series of EPBB2 indel driver mutations in non-small cell lung cancer identified by cell-free circulating tumor DNA NGS  
**AACR 2016 Abstract Nir Peled, Anna Bellowski-Rozencum, Lior Scoussan-Gutman, Christine Lee, AmirAli Talasz, Richard B. Lanman**

Detection rate of actionable mutations in diverse cancers using a biopsy-free (blood) circulating tumor cell DNA assay  
**Oncotarget, 2016 Maria Schwedler, Hatim Husain, Paul T. Fanta, David E. Piccioni, Santosh Kesari, Richard B. Schwab, Kimberly C. Banks, Sarah B. Lanman, AmirAli Talasz, Barbara A. Parker, Razele Kurczok**

Detection of Activating Estrogen Receptor 1 (ESR1) in Circulating Tumor DNA (ctDNA) in Hormone-Receptor Positive Metastatic Breast Cancer (MBC)  
**San Antonio Breast Cancer 2015 Symposium Abstract L. Austin, A. Rodriguez, R. Jaslow, P. Fortina, R. Nagy, O. Zill, A. Talasz, M. Cristofanilli**

Circulating Tumor DNA (ctDNA) for Detection of Molecular Residual Disease (MRD) in Breast Cancer  
**San Antonio Breast Cancer 2015 Symposium Abstract L. Austin, R. Jaslow, P. Fortina, R. Nagy, O. Zill, A. Talasz, M. Cristofanilli**

Cell-free DNA as molecular tool for monitoring disease progression and response to therapy in breast cancer patients  
**SABCS 2015 Liang DH, Patel A, Ensor JE, Patel TA, Chang JC, Rodriguez AA**

Impact of Multi Targeted Epigenetic Therapy (MTET): A Series of 100 Consecutive Advanced Solid Tumor Cancers  
**AACR 2015 Molecular Targets and Cancer Therapeutics Abstract M. A. Nezami, Steven Hager, Richard Lanman**

Circulating Cell-Free DNA As a Marker For Response and Resistance to BRAF and EGFR Inhibition in BRAF-Mutated Metastatic Colorectal Cancer  
**AACR 2015 Molecular Targets and Cancer Therapeutics Abstract Van Morris, Filip Janku, Helen Huang, Siqing Fu, Michael Overman, Sarina Pina-Paul, Vivek Subbiah, Bryan Kee, Apostola Tsimberidou, David Fogelman, Imad Shureiqi, Shanequa Manuel, Antonio Scarnardo, Richard Lanman, Nicolas Sommer, David Hong, Scott Kopetz**

Next-Generation Sequencing of Biopsy-Free Circulating Tumor DNA Revealed Frequent Actionable Alterations in Advanced Hepatocellular Carcinoma  
**AACR 2015 Molecular Targets and Cancer Therapeutics Abstract Sadakatsu Ikeda, Kimberly Banks, Richard B. Lanman, Razele Kurczok**

Differentiating Somatic and Germline Variants Using Targeted Next-Generation Sequencing (NGS) of Cell-Free Plasma DNA (cfDNA)  
**AACR 2015 Molecular Targets and Cancer Therapeutics Abstract Geoffrey R. Oxnard, Adrian G. Sacher, Ryan S. Alden, Nora B. Feeney, Jennifer C. Hang, Rebecca J. Nagy, Richard B. Lanman, Cloud P. Pawletz, Pasi A. Janne**

Development of EGFR C797S Mutation in Serial Liquid Biopsy Assessments in the Clinical Practice Setting  
**AACR 2015 Molecular Targets and Cancer Therapeutics Abstract Kathryn F. Mileham, Qing Zhang, Carol J. Farhangfar, Daniel E. Haggstrom, Stephen Fairclough, Oliver A. Zill, Daniel R. Carrizosa, Richard B. Lanman, Edward S. Kim**

Cell-free DNA (cfDNA) to Monitor Clonal Evolution in Patients with KRAS Wild-Type Metastatic Colorectal Cancer: Preliminary Results of a Phase I/II Clinical Trial of the Anti-MET Multi-Kinase Inhibitor Cabozantinib Plus the Anti-EGFR Monoclonal Antibody Panitumumab  
**AACR 2015 Molecular Targets and Cancer Therapeutics Abstract John H. Strickler, Tian Zhang, Andrew J. Armstrong, Donna Niedzwiecki, Hope E. Uronis, Michael A. Morse, S. Yousuf Zafar, Shao-Wen D. Hsu, Christy C. Arrowood, Rebecca Nagy, AmirAli Talasz, Richard Lanman, Sheri Haley, Herbert I. Hurwitz**

Genomic Profiling of Over 5,000 Consecutive Cancer Patients With a CLIA-Certified Cell-Free DNA NGS Test: Analytic and Clinical Validity and Utility  
**AACR 2015 Molecular Targets and Cancer Therapeutics Abstract Kimberly C. Banks, Stefanie A. W. Mortimer, Oliver A. Zill, Richard B. Lanman, Helmy Eltoukhy, AmirAli Talasz**

Analytical and Clinical Validation of a Digital Sequencing Panel for Quantitative, Highly Accurate Evaluation of Cell-Free Circulating Tumor DNA  
**PLoS ONE, 2015 Richard B. Lanman, Stefanie A. Mortimer, Oliver A. Zill, Dragan Sebanovic, Rene Lopez, Sibel Blau, Eric A. Collisson, Stephen G. Divers, Dave S. B. Hoon, Scott Kopetz, Jeeyun Lee, Petros Nikolaidis, Arthur M. Boca, Bahram G. Kermani, Helmy Eltoukhy, AmirAli Talasz**

A Multicenter, Open Label Phase II Clinical Trial of Combined MEK Plus EGFR Inhibition for Chemotherapy-Refractory Advanced Pancreatic Adenocarcinoma  
**Clinical Cancer Research, 2015 Andrew H. Ko, Tania Bekai-Saab, Jessica van Ziffle, Olga K. Mirzoeva, Nancy Joseph, AmirAli Talasz, Peter Kuhn, Margaret A. Tempero, Eric Collisson, Robin K. Kelley, Alan Venook, Elizabeth Dito, Anna Ong, Sharvina Ziyeh, Ryan Courtney, Regina Linetskaya, Sanaa Tahiri, and W. Michael Korn**

Cell-Free DNA Next-Generation Sequencing in Pancreatobiliary Carcinomas  
**Cancer Discovery, 2015 Oliver A. Zill, Cairo Greene, Dragan Sebanovic, Laimun Siew, Jim Leng, Mary Vu, Andrew E. Herdfar, Zhen Wang, Chloe E. Atreya, Robin K. Kelly, Katherine Van Loon, Andrew H. Ko, Margaret A. Tempero, Trevor G. Bivona, Pamela N. Munster, Amir Ali Talasz, Eric A. Collisson**

Biopsy-free comprehensive genomic profiling of over 5,000 cancer patients using a CLIA-certified commercial cell-free DNA next-generation sequencing test  
**ASHG 2015 S. Mortimer, O. Zill, J. Vowles, R. Lopez, D. Delubac, K. Dilger, R. Mokhtari, W. Chen, S. Bakhtiani, C. Jackson, T. Vo, B. Kermani, K. Banks, R. Nagy, A. Baca, R. Lanman, H. Eltoukhy, A. Talasz**

Clinical utility of a circulating cell-free DNA assay for clinical trial enrollment in refractory metastatic colorectal cancer patients  
**ASCO 2015 Abstract Van Morris, Maria P. Morelli, Michael Overman, Bryan Kee, David Fogelman, Eduardo Vilar, Imad Shureiqi, Christopher Garrett, Karwal Pagnay, Cathy Eng, Shanequa Manuel, Robert A. Wolff, Helmy Eltoukhy, Richard Lanman, Amir Ali Talasz, Scott Kopetz**

Predictors of clonal evolution in metastatic colorectal cancer patients  
**ASCO 2015 Abstract Pia Morelli, Michael Overman, Bryan Kee, Eduardo Vilar, Van Morris, David Fogelman, Imad Shureiqi, Chris Garre, Karwal Pagnay, Cathy Eng, Shanequa Manuel, Robert A. Wolff, Dragan Sebanovic, Laimun Siew, Aubrey Zapanta, Ben Schiller, Gangwu Mei, Helmy Eltoukhy, AmirAli Talasz, Scott Kopetz**

Analysis of cell-free circulating tumor DNA in patients with glioblastoma and other primary brain tumors  
**ASCO 2015 Abstract David Piccioni, Kimberly C. Banks, Richard B. Lanman, Brad Brown, Marlon Saria, AmirAli Talasz, Sandeep C. Pingle, Santosh Kesari**

Prospective clinical application of circulating cell-free DNA sequencing in metastatic colorectal cancer  
**AACR 2015 Abstract Maria Pia Morelli, Michael Overman, Eduardo Vilar, Van Morris, David Fogelman, Imad Shureiqi, Chris Garrett, Pagnay Karwal, Cathy Eng, Brian Kee, Shanequa Manuel, Robert Wolff, Dragan Sebanovic, Laimun Siew, Aubrey Zapanta, Ben Schiller, Gangwu Mei, Helmy Eltoukhy, AmirAli Talasz, Scott Kopetz**

Biopsy-free comprehensive tumor profiling of 2,000+ consecutive cancer patients using CLIA-certified commercial test and its clinical utility  
**AACR 2015 Abstract Eric Collisson, Stefanie Mortimer, Dragan Sebanovic, Reza Mokhtari, Somayeh Bakhtiani, Rene Lopez, Devi M. Gadda, Maria M. Vidano, Heena Patel, Bahram G. Kermani, Helmy Eltoukhy, Richard B. Lanman, AmirAli Talasz**

Next-generation sequence analysis of cell-free DNA in patients with chemotherapy refractory advanced pancreatic adenocarcinoma (PDAC) treated with selumetinib (AZD6244) and erlotinib  
**AACR 2015 Abstract Andrew H. Ko, Tania Bekai-Saab, Ryan Courtney, Olga K. Mirzoeva, Sharvina Ziyeh, Robin K. Kelley, Elizabeth Dito, Anna Ong, Regina Linetskaya, Margaret Tempero, Alan P. Venook, AmirAli Talasz, Wolfgang Michael Korn**

Clinical utility of circulating tumor DNA (ctDNA) in advanced and metastatic breast cancer  
**AACR 2015 Abstract Laura K. Austin, Rebecca Jaslow, Tiffany Avery, Paolo Fortina, Dragan Sebanovic, Laimun Siew, Aubrey Zapanta, AmirAli Talasz, Massimo Cristofanilli**

Concordance of circulating tumor DNA (ctDNA) and next-generation sequencing (NGS) as molecular monitoring tools in metastatic breast cancer (MBC)  
**AACR 2015 Abstract Laura K. Austin, Tiffany Avery, Rebecca Jaslow, Paolo Fortina, Dragan Sebanovic, Laimun Siew, Aubrey Zapanta, AmirAli Talasz, Massimo Cristofanilli**

Comparison of mutational spectra in metastatic tumors and cell-free DNA in breast cancer patients  
**AACR 2015 Abstract Kara N. Maxwell, Danielle J. Soucier-Ernest, Erica L. Carpenter, Andrea B. Troxel, Christopher Colanepo, Candace Clark, Michael D. Feldman, Bijal Kakria, Melissa Langer, Joy Lee, David A. Lewis, David Lieberman, Jennifer Morrisette, Tien-chi Pan, Stephanie S. Yee, Natalie Shin, Lewis A. Chodosh, Angela M. DeMichele**

Circulating tumor DNA (ctDNA) as a molecular monitoring tool in metastatic breast cancer (MBC)  
**Journal of Clinical Oncology, 32:5s 2014 (suppl; abstr 11093) Austin LK, Fortina P, Sebanovic D, Siew L, Zapanta A, Talasz A, Cristofanilli M**

Frequency of concurrent gene mutations and copy number alterations in circulating cell-free DNA (cfDNA) from refractory metastatic CRC patients  
**Journal of Clinical Oncology, 32:5s 2014 (suppl; abstr 11117) Morelli MP, Overman MJ, Sanchez EV, Morris VK, Shureiqi I, Garrett C, Fogelman D, Pratap K, Pagnay S, Kee BK, Zapanta A, Mei G, Schiller B, Eltoukhy H, Talasz A, Kopetz S**

Identification of multiple informative genomic mutations by deep sequencing of circulating cell-free tumor DNA in plasma of metastatic melanoma patients  
**Journal of Clinical Oncology, 32:5s 2014 (suppl; abstr 9018) Hoon DSB, Huang S, Sebanovic D, Siew L, Zapanta A, Mortimer S, Talasz A**

Use of Guardant360 noninvasive tumor sequencing assay on 300 patients across colorectal, melanoma, lung, breast and prostate cancers and its clinical utility  
**Journal of Clinical Oncology, 2014 (suppl; abstr e22041) Talasz A, Mortimer S, Sebanovic D, Siew L, Zapanta A, Mei G, Schiller B, Eltoukhy H**

Comprehensive non-invasive tumor sequencing: High fidelity sequencing of tumor-derived circulating cell-free DNA across 300 cancer patients  
**AACR 2014 Abstract Mortimer S, Sebanovic D, Mei G, Schiller B, Siew L, Zapanta A, Eltoukhy H, Talasz A**

Ultra-high quality sequencing assay for comprehensive genetic panel analysis of tumor-derived circulating cell-free DNA in colorectal patients  
**Journal of Clinical Oncology, 2014 (suppl 3; abstr 504) Lee J, Mortimer S, Sebanovic D, Mei G, Siew L, Eltoukhy H, Talasz A**

Ultra-high quality sequencing assay for comprehensive genetic panel analysis of tumor-derived circulating cell-free DNA  
**ASHG, Boston 2013 Talasz A, Sebanovic D, Mei G, Siew L, Eltoukhy H**

Liquid biopsy based assays to monitor residual disease in cancer  
**Journal of Clinical Oncology, 2013 (suppl; abstr 11095) Mei G, Sebanovic D, Mir A, Gulzar Z, Brooks JD, Jeffery SS, Talasz A**



# EXHIBIT 46

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA

GUARDANT HEALTH, INC.,  
a Delaware corporation,

Plaintiff/Counter-Defendant,

vs.

Case No. 3:17-cv-3590

FOUNDATION MEDICINE, INC.,  
a Delaware corporation,

Defendant/Counter-Plaintiff.

-----/

\* CONFIDENTIAL PURSUANT TO PROTECTIVE ORDER \*  
VIDEOTAPED DEPOSITION OF VICTORIA WANG, M.D., Ph.D.

San Francisco, California

Wednesday, January 17, 2018

Reported by:  
LORRIE L. MARCHANT, CSR No. 10523  
RMR, CRR, CCRR, CRC

Job No. 135724

1 Am I correct that in Exhibit 2, the pages  
2 24 through 27 are patient records of this  
3 41-year-old patient?

4 A. Correct. Correct.

5 Q. So this is the patient records for the  
6 person described in the letter to the editor that is  
7 Exhibit 3?

8 A. Correct.

9 Q. Okay. Can you tell from this the number of  
10 days between when the first cycle of chemotherapy  
11 happened and blood was drawn for the FoundationACT  
12 assay?

13 A. No. Because I don't have the date of this  
14 medical note.

15 Q. Which medical note? I see dates on it.  
16 I'm just -- when you say "I don't" -- what -- what  
17 note?

18 A. The date -- the date that this note was  
19 written. Because I see Cycle 1 was given on  
20 June 15th.

21 Q. Okay.

22 A. Okay. And I just do not know off the top  
23 of my head when this note was written.

24 Q. But if this says that Cycle 1 of the  
25 chemotherapy was on June 15th, doesn't that mean it

1 was on June 15th?

2 A. Right. That's Cycle 1 of chemotherapy.

3 But your question is how many days from Cycle 1 of  
4 chemotherapy to when FoundationACT was drawn.

5 Q. Oh. So you're saying you don't have the  
6 date for when you drew blood for FoundationACT on  
7 here?

8 A. Right.

9 Q. Okay.

10 A. I believe FoundationACT was drawn on the  
11 date this note was written, but there is no date of  
12 the note.

13 Q. Okay. Could you figure that out from your  
14 records?

15 A. Yes. Because I always put a very detailed  
16 plan, and in the plan I said:

17 "Consent was obtained for tumor  
18 banking and blood obtained for  
19 FoundationACT."

20 So I think I drew blood on the date this  
21 note was written for FoundationACT.

22 Q. Okay.

23 A. But the date of the note is not here.

24 Q. The June 15 date that is listed for  
25 Cycle 1, does that mean that Cycle -- the first

1 BY MR. PERLOFF:

2 Q. Correct?

3 A. Yes.

4 Q. And here you indicate that certainly as of  
5 July the 1st, you had drawn blood. And I say that,  
6 in the second paragraph:

7 "I just drew blood to send for FACT  
8 for comparison."

9 A. Okay.

10 Q. Do you see that?

11 A. Yes.

12 Q. So presumably --

13 A. Yes.

14 Q. -- sometime either on the 1st or just prior  
15 to the 1st --

16 A. It's probably on July 1st, then.

17 Q. Okay. Well, it says "drawn today"; right?

18 A. Okay.

19 Q. "I drew her blood to send for  
20 FACT for comparison; however, not best  
21 comparison because Guardant was sent prior  
22 to any treatment and FACT drawn today was  
23 after one cycle of chemo" --

24 A. Right.

25 Q. -- "because she was so symptomatic."

1 A. Right.

2 Q. So that gives you a sense that the blood  
3 that you drew for the FoundationACT was drawn  
4 probably on the 1st?

5 A. Yes.

6 Q. And Siraj Ali then wrote back to you, again  
7 on the same day, July the 1st -- actually, now that  
8 I'm looking at this, do you see how his response is  
9 11:46 a.m.?

10 A. M-hm.

11 Q. Is that because he's on the East Coast?

12 A. I don't know.

13 Q. Was Siraj Ali on the East Coast?

14 A. Well, Siraj, I believe is based in  
15 Cambridge, but he travels. And so I don't know  
16 where he is at any given time.

17 Q. Well, the reason I'm asking is if you look  
18 at the sequence of e-mails --

19 A. The timing is confusing.

20 Q. Yes.

21 A. Yeah, so I don't know.

22 Q. Okay. But do you recall -- if I'm correct,  
23 then, you would have responded not four hours later,  
24 but more like 40 minutes later.

25 So do you recall promptly responding to

## 1 DEPOSITION OFFICER'S CERTIFICATE

2 I, LORRIE L. MARCHANT, Certified Shorthand  
3 Reporter, Certificate No. 10523, for the State of  
4 California, hereby certify that VICTORIA WANG, M.D.  
5 was by me duly sworn/affirmed to testify to the  
6 truth, the whole truth and nothing but the truth in  
7 the within-entitled cause; that said deposition was  
8 taken at the time and place herein named; that the  
9 deposition is a true record of the witness's  
10 testimony as reported to the best of my ability by  
11 me, a duly certified shorthand reporter and a  
12 disinterested person, and was thereafter transcribed  
13 under my direction into typewriting by computer;  
14 that request [ ] was [ X ] was not made to read and  
15 correct said deposition.

16 I further certify that I am not interested  
17 in the outcome of said action, nor connected with,  
18 nor related to any of the parties in said action,  
19 nor to their respective counsel.

20 IN WITNESS WHEREOF, I have hereunto set my  
21 hand this 19th day of January, 2018.

22  
23 \_\_\_\_\_  
24 LORRIE L. MARCHANT, RMR, CRR, CCRR, CRC  
25 Certified Shorthand Reporter #10523

# EXHIBIT 47



**EXHIBIT 47**

**TO THE DECLARATION OF**

**AMANDA M. BARTLETT**

**To be Filed Under Seal**

# EXHIBIT 48

HIGHLY CONFIDENTIAL

Page 1

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF CALIFORNIA

---oOo---

GUARDANT HEALTH, INC.,  
a Delaware corporation,

Plaintiff,

vs.

No. 3:17-cv-3590

FOUNDATION MEDICINE, INC.,  
a Delaware corporation,  
Defendant.

\_\_\_\_\_ /

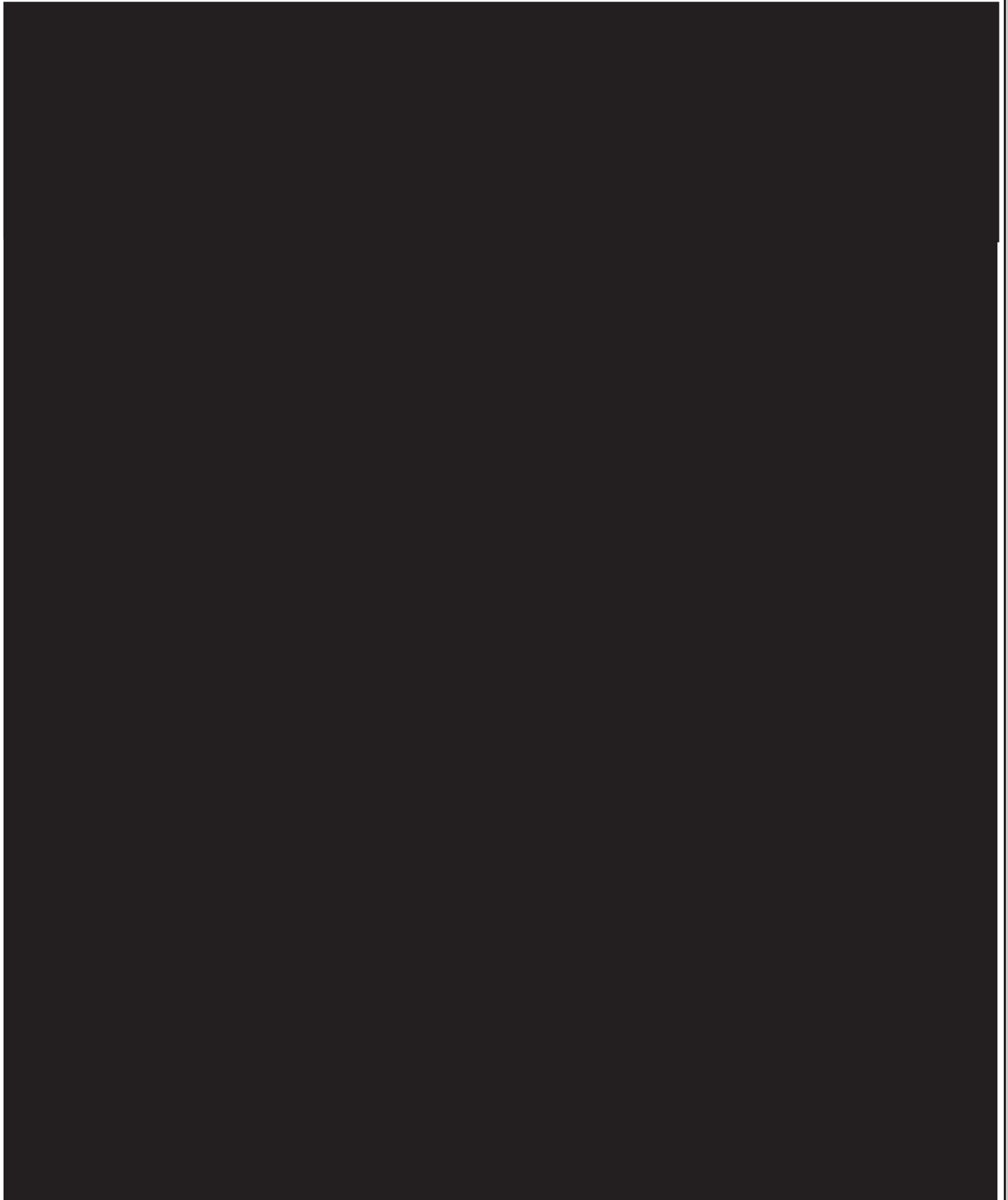
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VIDEOTAPED DEPOSITION OF PHILIP J. STEPHENS, Ph.D.  
SAN FRANCISCO, CALIFORNIA  
FRIDAY, FEBRUARY 16, 2018

BY: ANDREA M. IGNACIO, CSR, RPR, CRR, CCRR, CLR ~  
CSR LICENSE NO. 9830  
JOB NO. 136628

HIGHLY CONFIDENTIAL

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HIGHLY CONFIDENTIAL

Page 231



HIGHLY CONFIDENTIAL

Page 232



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Highly Confidential

Page 249

## 1 CERTIFICATE OF REPORTER

2  
3 I, ANDREA M. IGNACIO, hereby certify that the  
4 witness in the foregoing deposition was by me duly  
5 sworn to tell the truth, the whole truth, and nothing  
6 but the truth in the within-entitled cause;

7 That said deposition was taken in shorthand  
8 by me, a disinterested person, at the time and place  
9 therein stated, and that the testimony of the said  
10 witness was thereafter reduced to typewriting, by  
11 computer, under my direction and supervision;

12 That before completion of the deposition,  
13 review of the transcript [ ] was [x] was not  
14 requested. If requested, any changes made by the  
15 deponent (and provided to the reporter) during the  
16 period allowed are appended hereto.

17 I further certify that I am not of counsel or  
18 attorney for either or any of the parties to the said  
19 deposition, nor in any way interested in the event of  
20 this cause, and that I am not related to any of the  
21 parties thereto.

22 Dated: 2/20/18

23 \_\_\_\_\_  
24 ANDREA M. IGNACIO, RPR, CRR, CCRR, CLR, CSR No. 9830  
25



# EXHIBIT 49

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UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN FRANCISCO DIVISION

Case No. 3:17-cv-3590

- - - - - X

GUARDANT HEALTH, INC.,  
a Delaware corporation,  
Plaintiff,

v.

FOUNDATION MEDICINE, INC.,  
a Delaware corporation,  
Defendant.

- - - - - X

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VIDEO DEPOSITION OF SIRAJ MAHAMED ALI, M.D., Ph.D.  
Wednesday, January 24, 2018, 9:35 a.m.

Choate Hall & Stewart LLP  
Two International Place  
Boston, Massachusetts 02110

--- Reporter: Kimberly A. Smith, CRR, CRC, RDR ---  
Realtime Systems Administrator  
O'Brien & Levine Court Reporting Solutions

**Siraj Mahamed Ali - January 24, 2018**  
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**254**

06:25:28 1  
06:25:28 2  
06:25:32 3  
06:25:36 4  
06:25:36 5  
06:25:39 6  
06:25:44 7  
06:25:52 8  
06:25:53 9  
06:25:54 10  
06:25:55 11  
06:25:55 12  
06:25:59 13  
06:26:09 14  
06:26:14 15  
06:26:15 16  
06:26:16 17  
06:26:21 18  
06:26:28 19  
06:26:35 20  
06:26:44 21  
06:26:50 22  
06:26:55 23  
06:26:57 24



**MS. BARTLETT: Hold on one second. Can  
we get a time check?**

**Siraj Mahamed Ali - January 24, 2018**  
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06:32:44 1  
06:32:48 2  
06:32:54 3  
06:33:02 4  
06:33:09 5  
06:33:10 6  
06:33:12 7  
06:33:16 8  
06:33:19 9  
06:33:23 10  
06:33:28 11  
06:33:31 12  
06:33:35 13  
06:33:39 14  
06:33:49 15  
06:33:53 16  
06:33:57 17  
06:34:00 18  
06:34:01 19  
06:34:03 20  
06:34:06 21  
06:34:06 22  
06:34:07 23  
06:34:16 24



Siraj Mahamed Ali - January 24, 2018  
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06:34:17 1  
06:34:20 2  
06:34:25 3  
06:34:29 4  
06:34:31 5  
06:34:35 6  
06:34:40 7  
06:34:40 8  
06:34:41 9  
06:34:46 10  
06:34:48 11  
06:34:50 12  
06:34:52 13  
06:34:53 14  
06:34:58 15  
06:35:01 16  
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06:35:17 23  
06:35:22 24



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## C E R T I F I C A T E

I, Kimberly A. Smith, a Certified Realtime Reporter, Certified Realtime Captioner, Registered Diplomate Reporter, Realtime Systems Administrator, and Notary Public in and for the Commonwealth of Massachusetts, do hereby certify that the foregoing deposition of SIRAJ MAHAMED ALI, M.D., Ph.D., who was first duly sworn, taken at the place and on the date hereinbefore set forth, was stenographically reported by me and later reduced to print through computer-aided transcription, and the foregoing is a full and true record of the testimony given by the deponent.

I further certify that I am a disinterested person in the event or outcome of this cause of action.

THE FOREGOING CERTIFICATION OF THIS TRANSCRIPT DOES NOT APPLY TO ANY REPRODUCTION OF THE SAME BY ANY MEANS UNLESS UNDER THE DIRECT CONTROL AND/OR DIRECTION OF THE CERTIFYING COURT REPORTER.

Signed this 30th day of January, 2018.

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KIMBERLY A. SMITH, CRR, CRC, RDR

My commission expires: November 20, 2020

# EXHIBIT 50

**EXHIBIT 50**

**TO THE DECLARATION OF**

**AMANDA M. BARTLETT**

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# EXHIBIT 51



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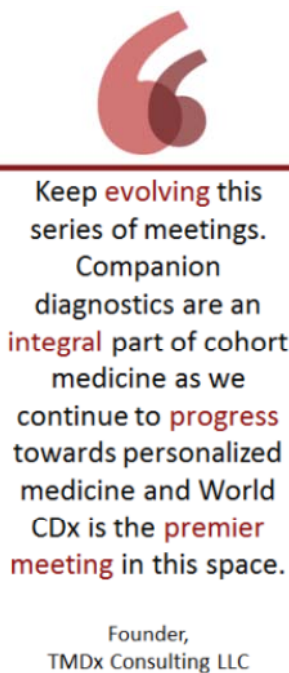
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Takeda



**Carl Barrett**  
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Astrazeneca



**Christina Bender**  
Director, Global Oncology, Diagnostic Pipeline Strategy  
Novartis



**Jason Christiansen**  
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Ignyta



**Rodolphe Clerval**  
Chief Business Officer & Vice President, US Operations  
Enterome Bioscience



**Benoit Destenaves**  
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AstraZeneca



**Emmanuelle di Tomaso**  
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Syros Pharmaceuticals



**Dan Dransfield**  
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Siamab Therapeutics



**Jakob Dupont**  
Vice President & Global Head, Breast & Gynecologic Cancer Development  
Genentech



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**Adam Berger**  
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**Chandra Branham**  
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**Khatereh Calleja**  
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Associate Director, Gastrointestinal Oncology Program  
The University of Chicago Medical Center

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Vice President & National Medical Director  
Aetna



**John Longshore**  
Director, Molecular Pathology, Carolinas Pathology Group  
Carolinas HealthCare System



**Stuart Martin**  
Professor  
University of Maryland, speaking on behalf of ANGLE plc



**Bill Pignato**  
Principal  
W.J. Pignato & Associates



**Ferran Prat**  
Vice President, Strategic Industry Ventures  
MD Anderson Cancer Center



**Joshua Xu**  
Principal Investigator, National Center for Toxicological Research (NCTR)  
FDA

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CSO  
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**Jason DeLoach**  
International Product Manager, CDx  
Ventana Companion Diagnostics



**Dan Edelstein**  
Director, Clinical Marketing & New Technology  
Sysmex Inostics



**Eric Faulkner**  
Vice President, Precision & Transformative Technology Solutions  
Evidera



**Jim Godsey**  
Vice President, R&D, Clinical Sequencing Division  
Thermo Fisher Scientific



**Karen Gutekunst**  
Vice President, Diagnostic Development  
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**Kalyan Handique**  
Chief Executive Officer & President  
Celsee Diagnostics

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Chief Pathologist, CDx Histopathology  
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**Claire Huguet**  
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**Patrick Hurban**  
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**David Kern**  
Senior Director, Regulatory Affairs  
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**Joseph Krueger**  
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Flagship Biosciences



**Hannah Mamuszka**  
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**Dawn McHugh**  
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Corgenix



**Matthew McManus**  
CEO  
Asuragen



**Susanne Munksted**  
Director, Global Commercial Alliances, Companion Diagnostics  
Agilent Technologies



**Michael Natan**  
CEO  
Ultivue



**Bill Powell**  
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**Scott Reid**  
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NeoGenomics Laboratories



**Mark Roberts**  
Senior Director, Diagnostics Development  
Covance

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**Christophe Roos**  
Chief Scientific Officer  
Euformatics, speaking on behalf of Horizon Discovery



**Craig Shimasaki**  
President & CEO  
Moleculera Labs



**Bob Silverman**  
Head of Externalized Drug Discovery Partnering  
Roche



**Elodie Sollier**  
Chief Scientific Officer  
Vortex Biosciences



**Vishal Sikri**  
US General Manager  
Biocartis



**John Simmons**  
Director, Translational Sciences & Diagnostics  
Personal Genome Diagnostics



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**Dan Snyder**  
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**Steen Thaarup**  
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Unilabs



**Tom Turi**  
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**Katarina Wikstrom**  
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#### VENUE DETAILS

Venue for 2018 to be confirmed  
MA, USA

#### ABOUT US

Hanson Wade's goal is to accelerate progress within organisations and across industries. Our primary method for achieving this is by creating exclusive business conferences that gather together the world's smartest thinkers and doers.

#### LOCATION



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# EXHIBIT 52

EXHIBIT 52  
TO THE DECLARATION OF  
AMANDA M. BARTLETT

**To be Filed Under Seal**

# EXHIBIT 53

# Specification Sheet

Biopsy-Free cancer management with a simple blood test



Guardant360® detects circulating tumor DNA (ctDNA) in blood specimens of advanced solid-tumor cancer patients. It identifies all actionable somatic genomic targets recommended by leading guidelines with a single blood draw. Guardant360's proprietary Digital Sequencing method nearly eliminates false positives.

- Complete sequencing of covered exons across 73 genes. Detects all four major classes of alterations including point mutations (SNVs), amplifications (CNAs), fusions, and indels relevant for patient care.
- Reports associated targeted treatment options including approved therapies and late stage clinical trials.
- Compared to other liquid biopsies, Guardant360 has more peer-reviewed publications, including clinical outcome studies.<sup>†</sup> Unlike tissue-based tests, Guardant360 allows for non-invasive comprehensive tumor genotyping in advanced cancer patients.

## Indications for use

Guardant360 is recommended for the following indications

- Advanced cancer patients requiring more complete genotyping
- Tissue biopsy is not sufficient in quantity or quality, or tissue is unobtainable at diagnosis or progression
- Progression of cancer as documented by functional status, imaging, or tumor markers
- Archived tissue older than 6 months
- One or more lines of therapy or intervention since last biopsy

## Other use cases

- Time to treatment is critical and decision needed in 2 weeks or less
- Patient prefers non-invasive genomic profiling or unwilling to submit to invasive biopsies

## Not indicated for use

- Hematologic malignancy
- Early stage solid tumor cancer (Stage I-II)
- Stable disease
- If possible, avoid testing during a cycle of chemo or radiation therapy

## Specifications

### Sample specifications

Sample type and volume	Two 10 mL tubes of whole blood
Storage and Shipping conditions	Store up to overnight, and ship same or next day at room temperature

### Guardant360 test specifications

Informed consent required	Yes
Requisition required	Yes
Methodology	Digital next-generation DNA sequencing
Test turnaround time	≤2 weeks from sample receipt to results
Genes tested	73 genes ( <i>see gene list</i> ).
Alterations reported	Point mutations (SNVs), amplifications (CNAs), fusions, and indels

Alterations	Reportable Range	Allelic Fraction/ Copy Number	Analytical Sensitivity	PPV*
SNVs	≥0.04%	>0.25%	>99.9%	99.6%
		0.05-0.25%	63.8%	92.1%
Indels	≥0.02%	>0.25%	>99.9%	98.0%
		0.05-0.25%	67.8%	88.4%
Fusions	≥0.04%	≥0.3%	100%	100%
		<0.3%	83.0%	100%
CNAs	≥2.12 copies	2.3 copies**	95.0%	100%

Based on cell-free DNA input of ≥30 ng in patient samples. Analytical sensitivity cited above are for targeted, clinically important regions. Sensitivity outside these regions or in highly repetitive sequence contexts may vary.

\*Over entire genomic reportable range of Guardant360 panel. \*\*Equivalent to 5% tumor fraction and 8 ERBB2 (HER2) gene copies in tumor. Copy number sensitivity may vary with other genes (2.28 - 2.49 copies).



## Complete Sequencing of Covered Exons\*

Point Mutations (SNVs) (73 Genes)						Indels (23 Genes)		Amplifications (18 Genes)		Fusions (6 Genes)	
AKT1	ALK	APC	AR	ARAF	ARID1A	ATM	ATM	APC	AR	BRAF	ALK
BRAF	BRCA1	BRCA2	CCND1	CCND2	CCNE1	CDH1	ARID1A	BRCA1	CCND1	CCND2	FGFR2
CDK4	CDK6	CDKN2A	CTNNB1	DDR2	EGFR	ERBB2 (HER2)	BRCA2	CDH1	CCNE1	CDK4	FGFR3
ESR1	EZH2	FBXW7	FGFR1	FGFR2	FGFR3	GATA3	CDKN2A	EGFR	CDK6	EGFR	NTRK1
GNA11	GNAQ	GNAS	HNF1A	HRAS	IDH1	IDH2	ERBB2	GATA3	ERBB2	FGFR1	RET
JAK2	JAK3	KIT	KRAS	MAP2K1/MEK1	MAP2K2/MEK2	MAPK1/ERK2	KIT	MET	FGFR2	KIT	ROS1
MAPK3/ERK1	MET	MLH1	MPL	MTOR	MYC	NF1	MLH1	MTOR	KRAS	MET	
NFE2L2	NOTCH1	NPM1	NRAS	NTRK1	NTRK3	PDGFRA	NF1	PDGFRA	MYC	PDGFRA	
PIK3CA	PTEN	PTPN11	RAF1	RB1	RET	RHEB	PTEN	RB1	PIK3CA	RAF1	
RHOA	RIT1	ROS1	SMAD4	SMO	STK11	TERT**	SMAD4	STK11			
TP53	TSC1	VHL					TP53	TSC1			
							VHL				

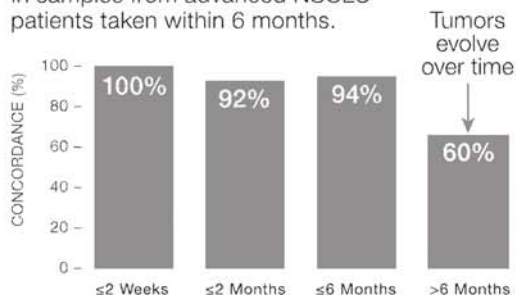
\* Available upon request.

\*\* Exons selected to maximize detection of known somatic mutations. List available upon request.

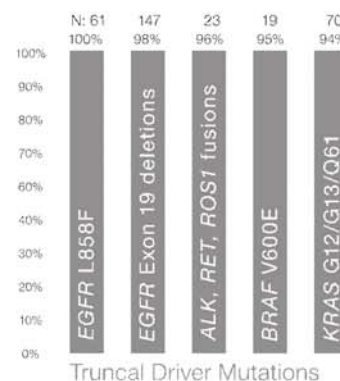
\*\* includes TERT promoter region

Guardant360 is clinically accurate<sup>1-6</sup>>90% Concordance with Matched Tissue<sup>5</sup>

In samples from advanced NSCLC patients taken within 6 months.

Accurate, even at low mutant allele fraction (MAF)<sup>6</sup>

Over half of alterations detected in patients by Guardant360 are below 0.4% MAF. In 398 patients with matched tissue sequencing results, across common driver mutations, Guardant360's PPV was 94%-100%, and remained high (94.5%) even for low MAF alterations (<0.5% MAF).



## Guardant360 has broad utility and proven clinical actionability

Highlights of NEXT-2 NSCLC prospective outcome study performed at Samsung Medical Center<sup>7</sup>

**193** Patients tested with Guardant360

**88%** Response rate of NSCLC patients (RECIST)

**60%** Response rate of Gastric cancer patients (RECIST)

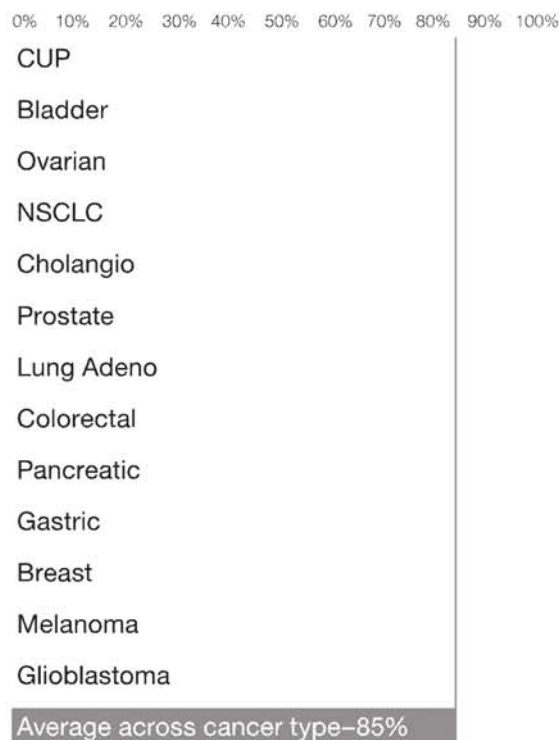
Highlights of NSCLC prospective outcome study performed at the University of Pennsylvania Perelman School of Medicine<sup>5</sup>

**102** Patients tested with Guardant360

**51%** Patients for whom tissue sequencing could not be performed

**8 of 10** Patients without tissue samples for whom Guardant360 detected an *EGFR* T790M mutation (ie. rescued patients)

**31%** Patients in whom Guardant360 detected alterations associated with FDA-Approved, on-label therapies

Clinical Detection Rate by Cancer Type<sup>8</sup>

Based on 5,000 clinical samples



REFERENCES 1. Lanman RB, et al. PLoS One. 2015;10(10):e0140712 | 2. Kim ST, et al. Oncotarget. 2015 Oct 5 | 3. Zill OA, et al. Cancer Discov. 2015 Jun 24 | 4. Ko AH, et al. Clin Cancer Res Off J Am Assoc Cancer Res. 2015 Aug 6 | 5. Thompson, et al. Clin Cancer Res, September 2016 d 10.1158/1078-0432.CCR-16-1231 | 6. Zill OA, et al. J Clin Oncol 34, 2016 (suppl; abstr LBA11501) | 7. Kim ST, et al. J Clin Oncol 33, 2015 (suppl; abstr e12540). | 8. Guardant Health Database 2016.

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TST-BRO-027 V4

GHI00037502

# EXHIBIT 54

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

Case No. 3:17-cv-3590

- - - - - X

GUARDANT HEALTH, INC.,

a Delaware corporation,

Plaintiff,

v.

FOUNDATION MEDICINE, INC.,

a Delaware corporation,

Defendant.

- - - - - X

VOLUME I

Pages 1-258

HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY  
VIDEO DEPOSITION OF GARRETT MICHAEL FRAMPTON, Ph.D.

Friday, January 26, 2018, 9:42 a.m.

Choate Hall & Stewart LLP

Two International Place

Boston, Massachusetts 02110

--- Reporter: Kimberly A. Smith, CRR, CRC, RDR ---

Realtime Systems Administrator

O'Brien & Levine Court Reporting Solutions

12:43:58 1

12:44:01 2

12:44:05 3

12:44:08 4

12:44:13 5

12:44:16 6

12:44:21 7 Q. One thing. Was Foundation Medicine CLIA  
12:44:26 8 certified at the time of commercial launch?

12:44:29 9 A. I believe so.

12:44:30 10 Q. My understanding is that in order to get a  
12:44:34 11 CLIA certification for a test, the laboratory has to  
12:44:42 12 provide the certifying agency data that validates  
12:44:47 13 the endpoints that are going to be reported by that  
12:44:50 14 diagnostic test.

12:44:51 15 Is that generally your understanding too?

12:44:53 16 A. With respect to CLIA validation, the bar is  
12:44:59 17 extremely low. And the amount of work and results  
12:45:07 18 that are required to receive CLIA validation is  
12:45:14 19 quite minimal and, in my opinion, insufficient with  
12:45:18 20 regard to a complicated cancer genomic profiling  
12:45:23 21 test to consider it validated.

12:45:25 22 But that's a -- "validated" is a word  
12:45:28 23 that has no -- you know, no agreed-upon definition.

12:45:34 24 Q. But is it your understanding that at least



12:45:43 1 from -- Well, does CLIA refer to it as validation?

12:45:46 2 A. Sure, yes.

12:45:48 3 Q. So is it at least your understanding that

12:45:50 4 from the --

12:45:52 5 A. I mean, that is an aspect of what they

12:45:54 6 certify.

12:45:55 7 Q. Right. And so to have a clean question and

12:45:58 8 answer, is it your understanding that in order to

12:46:00 9 get CLIA certification for, let's say, FoundationOne,

12:46:08 10 Foundation Medicine had to provide CLIA with

12:46:14 11 sufficient data that CLIA felt that that assay was

12:46:21 12 validated for each of the points that it would report

12:46:25 13 upon?

12:46:25 14 A. I'm not sure, no. I -- Probably not.

12:46:38 15

12:46:45 16

12:46:48 17

12:46:52 18

12:46:55 19

12:46:58 20

12:47:08 21

12:47:14 22

12:47:16 23

12:47:23 24

03:59:19 1 Does that happen at Foundation Medicine,  
03:59:23 2 where because performance of an assay is  
03:59:26 3 disappointing, you're involved in helping to make  
03:59:29 4 improvements?

03:59:30 5 MR. FEIGELSON: Object to form.

03:59:30 6 THE WITNESS: Myself personally?

03:59:33 7 BY MR. PERLOFF:

03:59:33 8 Q. Well, I guess anybody at FMI, but including  
03:59:36 9 yourself.

03:59:36 10 A. So --

03:59:37 11 MR. FEIGELSON: Object to form.

03:59:40 12 THE WITNESS: Sorry. Can you -- can you  
03:59:42 13 just restate.

03:59:45 14 BY MR. PERLOFF:

03:59:45 15 Q. Sure. Have you ever been asked at FMI to  
03:59:59 16 help work on improvements to any of its assays  
04:00:08 17 because the current performance of the assay was  
04:00:12 18 below expectation or not as good as FMI wanted it to  
04:00:16 19 be?

04:00:16 20 A. FMI wants its tests to be as absolutely  
04:00:24 21 good as is humanly possible. And we're constantly  
04:00:30 22 working to improve our tests.

04:00:31 23 Q. Have you been worked -- Have you worked at  
04:00:33 24 all on helping to improve FoundationACT?

## 1 C E R T I F I C A T E

2 I, Kimberly A. Smith, a Certified Realtime  
3 Reporter, Certified Realtime Captioner, Registered  
4 Diplomat Reporter, Realtime Systems Administrator,  
5 and Notary Public in and for the Commonwealth of  
6 Massachusetts, do hereby certify that the foregoing  
7 deposition of GARRETT MICHAEL FRAMPTON, Ph.D., who  
8 was first duly sworn, taken at the place and on the  
9 date hereinbefore set forth, was stenographically  
10 reported by me and later reduced to print through  
11 computer-aided transcription, and the foregoing is a  
12 full and true record of the testimony given by the  
13 deponent.

14 I further certify that I am a disinterested  
15 person in the event or outcome of this cause of  
16 action.

17 THE FOREGOING CERTIFICATION OF THIS TRANSCRIPT  
18 DOES NOT APPLY TO ANY REPRODUCTION OF THE SAME BY  
19 ANY MEANS UNLESS UNDER THE DIRECT CONTROL AND/OR  
20 DIRECTION OF THE CERTIFYING COURT REPORTER.

21 Signed this 2nd day of February, 2018.

22

23 \_\_\_\_\_  
KIMBERLY A. SMITH, CRR, CRC, RDR

24 My commission expires: November 20, 2020

# EXHIBIT 55

## Message

**From:** Annie Murphy [/O=FOUNDATION MEDICINE/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=ANNE MURPHY282]  
**Sent:** 1/8/2016 4:43:33 PM  
**To:** Garrett Frampton [/O=FOUNDATION MEDICINE/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Garrett Frampton788]; Travis Clark [/O=FOUNDATION MEDICINE/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Travis Clark7d1]; Mark Kennedy [/O=FOUNDATION MEDICINE/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Mark Kennedyb23]; Ramya Maddilate [/O=FOUNDATION MEDICINE/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Ramya Maddilatea0a]  
**Subject:** Re: [Update] FoundationACT market requirements  
**Attachments:** FACT v. Guardant 1-pager.docx

[Removed Matt, Geoff and Elaine]

Hi all,

Following up with this group regarding points 2 and 3 below. For launch, I would like to have a 1-pager which compares the attributes of our assay vs. Guardant360. The piece will incorporate the information available to us at launch and, therefore, will not be a true head to head. It is my expectation that we will conduct a true head to head post-launch. We should construct the 1-pager in a way that highlights our points of superiority in an objective way that is difficult for Guardant to combat and sets up the true H2H down the road. You may be thinking that it makes more sense to wait on a FACT v. G360 1-pager until we have true head to head data, but we expect Guardant to come directly at us in February and need to be prepared to pre-empt.

I propose we meet early next week to discuss the attached strawman with the goal of finalizing the piece for internal circulation by next Friday. Recognizing that everyone is busy, I would like to do this in the most efficient way possible. Travis/Mark, if you would like to flip a coin and decide who attends, that is fine. If you prefer that Garrett, Ramya and I take the first crack and send to you for edits, that's fine too.

Thanks in advance,  
 Annie

---

**From:** Garrett Frampton  
**Date:** Wednesday, December 16, 2015 at 2:24 PM  
**To:** Anne Murphy, Travis Clark, Mark Kennedy, Ramya Maddilate  
**Cc:** Matt Franklin, Geoff Otto, Elaine Labrecque  
**Subject:** RE: [Update] FoundationACT market requirements

For me a few other take away items were;

- 1) <!--[if !supportLists]--><!--[endif]-->We should market the excellence and experience of Foundation Medicine as an organization as a major differentiator of our ctDNA test.
- 2) <!--[if !supportLists]--><!--[endif]-->We should put together a technical document comparing Guardant's validation study to the study that we perform.
- 3) <!--[if !supportLists]--><!--[endif]-->We should strongly consider and plan for a head-to-head comparison of Guardant360 versus FoundationACT.

-Garrett

---

**From:** Annie Murphy  
**Sent:** Wednesday, December 16, 2015 2:05 PM  
**To:** Travis Clark; Mark Kennedy; Garrett Frampton; Ramya Maddilate

**Cc:** Matt Franklin; Geoff Otto; Elaine Labrecque

**Subject:** [Update] FoundationACT market requirements

Hi team,

Thanks for meeting this morning to identify our “competitive hooks” against Guardant (slides attached). Our first task was to confirm the product criteria required for the clinical market. We determined as a team that the current product is the right product for the clinical market. While customers may claim they would be satisfied with a lower spec than ours and are happy with Guardant, a lower quality assay, it is in the best interest of patients to maintain our high standards for FoundationACT. As we gain experience in the market and expand our data set of cases, [REDACTED]

[REDACTED] but we are not comfortable making such a decision at this point in time.

[REDACTED] The team determined that this goal can be achieved in ways. [REDACTED]

[REDACTED] No doubt, this will be the topic of further discussion, we can move forward toward February 15th knowing that the requirements for the clinical product will remain unchanged.

If I’ve mischaracterized anything from our meeting, please let the team know and please reach out with any additional questions.

Thanks,

Annie

--

**Annie Murphy**

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# EXHIBIT 56



“Our validation studies” video with Dr. Lanman

Video available at <http://guardanthealth.com/guardant360/> (last visited December 22, 2017) and <https://vimeo.com/149365747> (last visited December 22, 2017):

- 0:01 We’re very excited that our validation studies for the Guardant360 test have now come out in the scientific journal PLOS One.
- 0:09 The fundamental finding in this paper is a comparison of the simple non-invasive blood test doing next-gen sequencing on 165 samples from patients with advanced solid tumor cancers of a wide variety compared to tissue; tissue-based next-gen sequencing.
- 0:26 Samples were collected at UC San Francisco, MD Anderson Cancer Center, John Wayne Cancer Institute, Samsung Medical Center in Seoul, Korea, and from two large community-based health care systems, one in Georgia and one in Washington State.
- 0:41 So this multi-center study found that, number one, the Guardant360 test has exquisite sensitivity. We can detect small bits of circulating tumor DNA that have been shed by your tumor into your blood down to a single molecule or two in a 10 ML tube of blood. This is equivalent to a 0.1% or 1 in 1,000 parts mutant allele fraction.
- 1:04 The method it uses digital sequencing, where first we label the mutated DNA that we isolate from the blood sample. We label it with seven nucleotide tags; heptameric oligonucleotide descriptors. It’s like barcoding the DNA. So imagine circulating cell-free DNA, about 167 bases long, double stranded. Each strand, each complementary strand, labeled separately. All of that gets sequenced.
- 1:32 Post sequencing, if one of those two strands has picked up a false positive and the two strands don’t match any more, because of their labels, we know which strand goes with which strand, we can use algorithms to clean up the false positives.



- 1:45 The results is the best specificity of any next-gen sequencing or NGS method—not just blood-based NGS—but even tissue-based NGS. It's greater than 99.9999% specificity.
- 1:59 Now, the sensitivity is imperfect. It's high, but it's imperfect. This is because all tumors don't release their DNA into blood. So although we can detect a single molecule or two of mutated DNA in a 10 ML tube of blood, some of these tumors, even the advanced ones, may not release.
- 2:17 So, blood versus tissue? 85% sensitivity for Guardant360. The other fascinating finding was, when we looked at how did tissue next-gen sequencing perform versus the blood test, the tissue test missed 20% of the mutations that we found with the blood.
- 2:32 Now, why is that? That's because needle biopsies of deep cancers are limited by tumor heterogeneity. These tumors are multi-clonal. The needle biopsy can't possibly capture all the clones. Even if I surgically remove the lesion, there may be multiple lesions in metastatic cancers, and as we know now, these different clones in different metastases have different genomic signatures.
- 2:57 The blood test may act as a summary for all parts of a tumor and all metastases of a tumor. Which test would you use first? At progression, I would use the non-invasive test first. You're going to get a result in two weeks. If nothing is detected, by all means do the tissue biopsy.
- 3:14 On the first 1,000 Guardant360 tests run in actual clinical practice, the test almost never fails. There was a 99.8% pass rate. This contrasts with a 20-25% failure rate with tissue-based sequencing because you get a note back, there wasn't enough tissue to sequence, there weren't enough tumor cells on the slides, please reschedule a repeat biopsy.
- 3:38 Finally, when we compared the two methods, blood-based next generation sequencing to tissue-based sequencing for the genes in the Guardant360 panel, both tests had equivalent diagnostic accuracy, 99.399% plus diagnostic accuracy.
- 3:55 So, both tests highly accurate. Both tests with near perfect specificity. Both with high sensitivity, but imperfect. But one, only one of the two tests non-invasive. That's the difference between tissue-based sequencing and plasma-based digital sequencing with Guardant360.
- 4:14 To find all of our validation studies, please visit [GuardantHealth.com](http://GuardantHealth.com) forward-slash oursience.

# EXHIBIT 57

**EXHIBIT 57**

**TO THE DECLARATION OF**

**AMANDA M. BARTLETT**

**To be Filed Under Seal**

# EXHIBIT 58

**EXHIBIT 58**

**TO THE DECLARATION OF**

**AMANDA M. BARTLETT**

**To be Filed Under Seal**